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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/310,667	05/12/1999	DAVID J. ECKER	IBIS-0012	9164

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/310,667

Applicant(s)

ECKER ET AL.

Examiner

Frank W Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/1/2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29,35-41 and 43-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29,35-41 and 43-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 01 May 2003 is: a) ☐ approved b) ☒ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1634

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's RCE and the amendment filed on May 1, 2003 have been entered. The claims pending in this application are claims 27-29, 35-41, and 43-67. Rejection and/ or objection not reiterated from the previous office action are hereby withdrawn. The following rejections are based on amendment.

Drawings

2. The corrected drawings submitted on May 1, 2003 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The added or deleted materials in Figures 4 and 5A which are not supported by the original disclosure is as follows:

- (1) in the corrected Figure 4, there is no connection between "Annotations Relational Database" and "Filter & Sort" which is shown in original filed Figure 4.
- (2) in the corrected Figure 5A, "Is Weighted Percent of Matches at Point in Compare Better than Corresponding Point in bestArray?" in original filed Figure 5A is replaced with "Weighted Percent

Art Unit: 1634

of Matches at better than corresponding point in bestArray? The meanings of two phrases are different.

(3) in the corrected Figure 5A, "Set Point in bestArray to Weighted Match Percent" in original filed Figure 5A is replaced with "Set Point in bestArray =Weighted Match%". The meanings of two phrases are different.

Applicant is required to cancel these new matters in the reply to this Office Action.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see ncbi.nlm.nih.gov/Omim/. CGAP in page 12, line 1 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The disclosure is objected to because of the following informality: applicant is required to update priority information for US application 09/760,440 in the first sentence of the specification (substituted specification) filed on October 21, 2002 since US application 09/760,440 now is US patent No. 6,221,587.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1634

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-29, 35-41, and 43-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (for example, see page 32-44) provides adequate written descriptions for iron response element in 5' untranslated region of ferritin mRNA and in 3' untranslated region of transferrin receptor mRNA, 3' untranslated regions of histone and vimentin mRNAs, and 5' and 3' untranslated regions of mRNAs from ornithine decarboxylase, interleukin-2 and interleukin-4. However, the specification fails to adequately describe: (1) any kind of oligonucleotide comprising a molecular interaction site in RNA of a selected organism and in RNA of at least one additional organism wherein said molecular interaction site serves as a binding site for at least one molecule, wherein binding of said molecule to said molecular interaction site modulates the

Art Unit: 1634

expression of said RNA in said selected organism and wherein said oligonucleotide does not comprise an iron response element as recited in claims 35-41 and 43-67; and (2) any kind of oligonucleotide comprising a molecular interaction site that is present in prokaryotic RNA and in at least one additional prokaryotic RNA wherein said molecular interaction site serves as a binding site for at least one molecule, wherein binding of said molecule to said molecular interaction site modulates the expression of said prokaryotic RNA and wherein the binding of said molecule to said molecular interaction site does not modulate translation of said RNA. The claimed inventions as a whole are not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed inventions as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, in view of the teachings in the specification, claims 35, 51, 52, and 67 are read as any kind of oligonucleotide comprising a molecular interaction site in RNA of a selected organism and in RNA of at least one additional organism wherein said molecular interaction site serves as a binding site for at least one molecule, wherein binding of said molecule to said molecular interaction site modulates the expression of said RNA in said selected organism and wherein said oligonucleotide does not comprise an iron response element. Claim 27 is read as any kind of oligonucleotide comprising a molecular interaction site that is present in prokaryotic

Art Unit: 1634

RNA and in at least one additional prokaryotic RNA, wherein said molecular interaction site serves as a binding site for at least one molecule, wherein binding of said molecule to said molecular interaction site modulates the expression of said prokaryotic RNA and wherein the binding of said molecule to said molecular interaction site does not modulate translation of said RNA. Since independent claims 35, 51, 52, and 67 are directed to a product and are not directed to a method and it is well established that the determination of the patentability of the product is based on the product itself and is not dependent on the method for identifying the product, the method as recited in claims 35, 51, 52, and 67 is not read into claims. Since it is known in the art that iron response elements from ferritin mRNAs from different species and human transferrin receptor have a highly conserved six-membered loop (Harrison *et al.*, Biochim. Biophys. Acta, 1275, 161-203, 1996, see page 186, Figure 12) and a sequence of 28 nucleotides within putative stem-loops in the 5'-UTR of H- and L-ferritin mRNA of human, bullfrog, chicken, rabbit and the somal ferritin of the snail *Lymnaea stagnalis* as well as in rat is highly conserved and this sequence has been demonstrated to be essential (and sufficient) for the translational response to iron (Harrison *et al.*, Biochim. Biophys. Acta, 1275, 161-203, 1996, see page 187, right column, first paragraph), iron response element is an oligonucleotide comprising a molecular interaction site in RNA of a selected organism and in RNA of at least one additional organism wherein said molecular interaction site serves as a binding site for at least one molecule (ie. iron) and wherein binding of said molecule to said molecular interaction site modulates the expression of said RNA in said selected organism. Although the specification adequately describes 3' untranslated regions of histone and vimentin mRNAs and 5' and 3' untranslated regions of mRNAs from ornithine

Art Unit: 1634

decarboxylase, interleukin-2 and interleukin-4, the specification does not adequately describe whether there is a molecular interaction site in a region selected from 3' untranslated regions of histone and vimentin mRNA, and 5' and 3' untranslated regions of mRNAs from ornithine decarboxylase, interleukin-2 and interleukin-4 wherein the molecular interaction site is present in RNAs of at least two different organisms and binding of a molecule to the molecular interaction site modulates the expression of said RNAs in said organisms. Since the specification defines "Modulation" as "augmenting or diminishing RNA activity or expression" (see the specification, page 10, last paragraph), a well known "Shine & Dalgarno" sequence that is present in mRNAs from different bacteria can not be considered as a molecular interaction site as recited in claims 27-29 since "Shine & Dalgarno" sequence does not augment or diminish RNA activity or expression (also see applicant's remarks, page 5, first paragraph). In view of the teachings in the specification, it is unclear, besides iron response element, whether an oligonucleotide comprising a molecular interaction as recited in claims 27-29, 35-41, and 43-67 exists. Therefore, claims 27-29, 35-41, and 43-67 encompass numerous unknown and unidentified oligonucleotides that miss from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all oligonucleotides recited in claims 27-29, 35-41, and 43-67 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d

Art Unit: 1634

1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only iron response element meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 35-41 and 43-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 35, 52, and 67 recite the limitation "the iron response element or the 3' untranslated region of the histone mRNA" in the claims. There is insufficient antecedent basis for this limitation in the claim since the claims do not describe "iron response element or 3' untranslated region of histone mRNA" before the limitation "the iron response element or the 3' untranslated region of the histone mRNA" and there is no iron response element or 3' untranslated region of histone mRNA in an oligonucleotide as recited in claims 35, 52, and 67. The examiner

Art Unit: 1634

suggests that applicant changes “the iron response element or the 3' untranslated region of the histone mRNA” to “iron response element or 3' untranslated region of histone mRNA” in order to overcome the rejection.

10. Claim 51 recites the limitation “the iron response element” in the claims. There is insufficient antecedent basis for this limitation in the claim since the claims do not describe “iron response element” before the limitation “the iron response element” and there is no iron response element in an oligonucleotide as recited in claim 52. The examiner suggests that applicant changes “the iron response element” to “iron response element” in order to overcome the rejection.

Conclusion

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

Frank Lu
June 26, 2003